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Date 3-19-2007 Dora Rios

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Lewis, et al.	)	Confirmation No. 9722
Serial No.: 09/812,704	)	Examiner: Christopher Gilligan
Filed: March 19, 2001	)	Group Art Unit: 3626
For: ***METHODS AND SYSTEMS FOR HEALTHCARE PRACTICE MANAGEMENT***	)	Attorney Docket No. 044258.000003

DECLARATION UNDER 37 CFR 1.132

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Commissioner for Patents
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I, Richard G. Fiscella, state the following:

1. I have a Bachelor of Science, in Pharmacy (1976) degree and a Master of Public Health (1985) degree. I am a Registered Pharmacist, having extensive experience in pharmacology and in academia. I have published over eighty research or review papers with an emphasis in ophthalmology, infectious diseases and pharmacoeconomics. I have been the principal or co-investigator on numerous animal and human studies; researcher and speaker for several major pharmaceutical companies and since 1982 have participated in over one hundred ocular pharmacology presentations. Moreover since 1981, I have held several professorships in pharmacy practice. I hold numerous memberships in professional societies one of which is the Academy of Managed Care Pharmacy. I currently am a Clinical Professor in the Department of Pharmacy Practice for the University of Illinois.

2. I am familiar with and understand the subject matter of the above-identified patent application ("Lewis Application"). I have studied the application and the amendments to the application and the cited patent documents of record in the application.

3. I have read and studied the dissertation "The Effects of Hospital Contracting for Physician Services on Hospital Performance" (hereinafter "Snail") attached at Exhibit A, which examines the fundamental change in hospital contracting for physician services in the 1990s. I have also read and studied U.S. Patent No. 6,000,828 (hereinafter "Leet"), attached at Exhibit B, which provides a computer implemented method and system for improving drug treatment of patients in local communities by providing drug treatment protocols for particular disease states.

4. In my opinion, the present claimed invention, Claims 1-37, 39-46 and 51-56, advantageously provides a system and method for managing a healthcare practice which enhances profitability of the healthcare practice and is unique and operationally quite different than other systems and methods I have seen before and as set forth in the patent documents at Exhibits A and B. It is my opinion that the claimed invention, Claims 1-37, 39-46 and 51-56 would not be obvious to one of ordinary skill in the art at the time this application was filed. It is also my opinion that one skilled in the art would lack motivation to combine Snail and Leet to somehow arrive at the claimed invention.

5. I, however, also offer the following more detailed comments on these issues as well:

5a. Present Claimed Invention: The present claimed invention, Claims 1-37, 39-46 and 51-56, advantageously provide systems and methods related to physician behavior management for physicians within a healthcare practice participating in an insurance network (open, out-patient environment) designed to increase profitability of the individual physician, the healthcare practice and/or the insurance network, that is unique and operationally quite different than other systems and methods as set forth in the cited documents. Various claimed embodiments, for example, include: a method of managing a healthcare practice participating in an insurance network to enhance profitability of the healthcare practice with respect to a predetermined reimbursement amount for pharmacy costs; a method of optimizing the profitability of an insurance network having a plurality of physicians in a healthcare practice participating therein by managing ancillary medical costs; a healthcare management optimization

system for a healthcare practice including a plurality of physicians participating in an insurance network; and a healthcare management optimization system for a healthcare practice including a plurality of physicians participating in an insurance network. In particular, for example, Claim 1 includes the solution for managing a healthcare practice to enhance profitability of the healthcare practice, by gathering data in a computer medium on ancillary pharmacy costs for each of a plurality of physicians in a healthcare practice participating in an insurance network, identifying at least one of the physicians that is at a greater risk of not getting reimbursements by prescribing medications that are detrimental to receiving reimbursement, and substantially reducing the risk of not receiving the predetermined reimbursement amount for the ancillary pharmacy costs from the insurance network to increase the profitability of the healthcare practice by modifying management behavior for those at risk of not receiving reimbursement. Also, for example, as in Claim 13, the solution can be applicable to other ancillary medical costs; and as in Claim 25, the solution can have a financial incentive to the insurance network and physicians in the healthcare practice. Also for example, as in Claims 37 and 46, the solution can be applicable to and implemented by a computer system.

5b. Recognition of the Problem and the Source of the Problem.

5b1. It is my opinion that neither Snail nor Leet recognize the specific problems or the source of the problems, as identified, addressed and solved by the claimed embodiments of the Lewis et al. invention. That is, neither Snail nor Leet recognize, for example, ancillary pharmacy costs management behavior or other ancillary medical costs management behavior of physicians of a healthcare practice participating in an insurance network as the source of the problems of, for example, maintaining profitability of the healthcare practice and/or the insurance network. Snail, as a whole, teaches the effects of hospital contracting for physician services on hospital performance. Leet, as a whole, teaches a methodology of improving drug effectiveness for a specific treatment for a specific populace by determining emerging patterns of microbial drug resistance in a community and altering patterns of antimicrobial prescribing to reduce, and thus, solves the problem of microbial evolutionary pressures that produce resistant organisms. In contrast, claimed embodiments of the Lewis Application provide methods of and systems for enhancing profitability with respect to ancillary medical and ancillary pharmacy costs of a healthcare practice participating in an insurance network (open healthcare system).

Particularly, it appears from the background section of the Lewis Application that the inventors recognized that physicians in a healthcare practice participating in an insurance network were having difficulty maximizing reimbursements due to the amount of management, organization, time, and/or initiative necessary to follow the requirements of the insurance network and/or multiple insurance networks each having a different set of requirements, which would need to be complied with in order to maximize such reimbursements.

5b2. Additionally, both Snail and Leet apply only to hospitals or closed healthcare systems, where the claimed embodiments of Applicants invention apply to outpatient care or open healthcare systems. *See* Snail, abstract (summarizing the content of the article), and Leet, Fig. 2, title, and col. 18, lines 26-48 (describing implementation of the Leet computerized medical record system). This distinction, known and readily recognized by those skilled in the art, is an important distinction because closed healthcare systems have different procedures, rules, and governing regulations, along with different authorization, management, and record-keeping requirements, than that of open healthcare systems. The problems faced, and corresponding solutions created, are simply not generally directly readily transferable due to such significant disparities. For this reason, it is my opinion that persons of ordinary skill in the art who endeavor to develop either the claimed solutions or alternative solutions to the problems apparently recognized by Lewis et al. would not seek out Snail nor Leet, which both alone, and in combination, do not recognize both the problems solved by the Lewis et al.'s claimed methodologies or their source.

5c. Lack of Motivation to Combine References: It is my opinion that the claimed embodiments of the Lewis et al. invention would not be obvious to one of ordinary skill in the art, and one of ordinary skill in the art would not be motivated to combine Snail with Leet. These documents provide no explicit or implicit motivation to combine nor is there motivation to do so in the problems to be solved by either Snail or Leet, or the knowledge of one skilled in the art at the time of the invention. More specific comments on this issue follow.

5c1. Neither Snail nor Leet, alone or in combination, is directed to a system or method of managing a healthcare practice participating in an insurance network to enhance profitability of the healthcare practice with respect to a predetermined reimbursement amount for ancillary pharmacy or ancillary medical costs. Snail, as a whole, teaches the effects of hospital contracting for physician services on hospital performance. Leet, as a whole, teaches a

methodology of improving drug effectiveness for a specific treatment for a specific populace by determining emerging patterns of microbial drug resistance in a community and altering patterns of antimicrobial prescribing to reduce, and thus, solves the problem of microbial evolutionary pressures that produce resistant organisms. In contrast, embodiments of Lewis et al.'s claimed invention, as a whole, teach methods of and systems for enhancing profitability with respect to ancillary medical and ancillary pharmacy costs of a healthcare practice participating in an insurance network (*open* healthcare system). Additionally, neither Snail nor Leet are reasonably pertinent to the particular problem described in the Lewis Application. Both Snail and Leet apply only to hospitals or *closed* healthcare systems where the claimed embodiments of Lewis et al.'s invention apply to outpatient care or open healthcare systems. This distinction is known and readily recognized by those skilled in the art. This distinction is important because *closed* healthcare systems have different procedures, rules, and governing regulations, along with different procedures, authorization, management, and record-keeping requirements than that of *open* healthcare systems. As such, the teachings of one simply are not generally directly readily transferable to the other, due to such significant disparities. Therefore, it is my opinion that the combined teachings, knowledge of one of ordinary skill in the art, and nature of the problems to be solved, as a whole (enhancing profitability of a healthcare practice participating in an insurance network regarding management of ancillary medical costs), do not suggest combining these disparate references, as the combination would not solve the problems faced by Lewis et al.

5c2. It is also my understanding and opinion that the Examiner's statements that it would have been obvious to incorporate a computer tangible medium into the system of Snail to "reduce[e] the amount of paper records needed by Snail by automating the data collection process" (see paper No. 20070108A, para. 5) are also insufficient to establish obviousness, even assuming the combination would actually solve the problems (which it would not), and even assuming a motivation and an ability to combine the references, as there is no suggestion as to the desirability of such combination. First, there is no explicit or implicit suggestion as to the desirability of the combination. One must keep in mind that Snail is a dissertation discussing the effects of "hospital contracting" for physician services on "hospital performance," rather than on solving healthcare practice profitability issues. *See* Snail, abstract, para. 1. Leet provides a computer-based tool that can be used to recommend drug treatments which are allowed to evolve in response to changing medical information, side effects encountered, and patterns of disease

resistance, to thereby recommended treatments; evaluate drug treatments to help improve drug treatments in the community in which the treatment is being provided; detect emerging patterns of microbial drug resistance in a community; and alter patterns of antimicrobial prescribing to reduce microbial evolutionary pressures that produce resistant organisms. *See* Leet, col. 3, lines 10-25. Clearly, there is a significant disparity in the teachings of Snail and Leet. As such, it is my opinion that such disparate teachings would not have suggested to one of ordinary skill in the art that combining reference teachings would be desirable or lead to a desirable result.

5c3. Further, it is my belief that the Examiner has overlooked an important point that the motivation to combine references must be to produce a "proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter." Even if Snail and Leet could be combined, because Snail (*closed* healthcare system) is so clearly directed outside the field of Applicants endeavor (*open* healthcare system), the combination would not be expected to produce the claimed embodiments of Lewis et al.'s invention. As such, one skilled in the art would not be motivated to combine these disparate documents to try to produce the claimed embodiments of Lewis et al.'s invention.

5d. No Reasonable Expectation of Success.

5d1. Even if the teachings of Snail and Leet could be combined to try to assemble the claimed embodiments of Lewis et al.'s invention, neither Snail nor Leet teach gathering data regarding physicians in a healthcare group in a tangible computer medium. Leet was apparently introduced in the Office Action, paper No. 20070108A, para. 5, because "Snail does not explicitly disclose [such] a tangible computer medium for gathering the data regarding the physicians." Leet, however, also does not disclose or teach such feature. Rather Leet discloses gathering data regarding specific diseases and treatment in order to form an intelligent diagnostic tool which can provide *to* a physician a recommended treatment including comparative drug costs, predicted total number of unit doses, and projected total cost of administering each recommended treatment. *See* Leet, col. 3, line 41 to col. 4, line 41. This is not the same as gathering in a tangible computer medium from [(regarding)]...physicians in a healthcare practice...ancillary medical or pharmacy costs data, identifying certain physicians from the tangible computer medium..., or modifying management behavior of at least one...physician...." Without recognition of the source of the problems identified and addressed

by the inventors in the Lewis Application, Snail and Leet apparently could not know, and therefore did not disclose or teach such feature in order to solve such problems. Thus, without this missing feature, the combination could not produce the claimed embodiments of Lewis et al.'s invention.

5d2. Further, even if Snail and Leet could be combined and that either one or both documents suggested such desirability, as noted previously, because Snail (*closed* healthcare system) is so clearly directed outside the inventors' field of endeavor (*open* healthcare system), the combination could not be expected to produce the claimed embodiments of the invention. This important point was apparently overlooked by the Examiner. As such, it is my opinion that there is no reasonable expectation of success that the proposed combination would produce the claimed subject matter.

5e. Snail and Leet Do Not Teach or Suggest All the Claim Elements. It is my opinion that neither Snail nor Leet, alone or in combination, teach or suggest all of the elements of the claimed embodiments of the invention, independent Claims 1, 13, 25, 37, and 46, and their corresponding dependent claims. More specific comments on this issue follow.

5e1. Snail examined fundamental change in hospital (*closed* healthcare system) contracting for physician services in the 1990s. In contrast, embodiments of the claimed invention offer a solution for controlling costs and managing associated physician behavior to enhance physician, healthcare practice, and/or insurance network profitability, applicable only to an *open* healthcare system.

5e2. The Examiner specifically references Appendix 2 of Snail for the premise that Snail, in general, teaches the identifying and the modifying steps of, for example, Claim 1, and references Leet, col. 15, lines 11-28, for the premise that Leet teaches the gathering step. It is my opinion that the Examiner is mistaken. Snail does not provide a teaching of even the subject matter identified in the preamble of the independent claims, much less the specific elements of the independent claims. Claim 1, for example, features a method of managing a healthcare practice participating in an insurance network to enhance profitability of the healthcare practice with respect to a predetermined reimbursement amount for pharmacy costs--a solution for managing a healthcare practice to enhance profitability of the healthcare practice. To accomplish this method, Claim 1 features, at least in part, gathering data in a computer medium on ancillary pharmacy costs for each of a plurality of physicians in a healthcare practice

participating in an insurance network, identifying at least one of the physicians that is at a greater risk of not getting reimbursements by prescribing medications that are detrimental to receiving reimbursement, and substantially reducing the risk of not receiving the predetermined reimbursement amount for the ancillary pharmacy costs from the insurance network to increase the profitability of the healthcare practice by modifying management behavior for those at risk of not receiving reimbursement. Also, for example, as in Claim 13, the solution can be applicable to other ancillary medical costs; and as in Claim 25, the solution can have a financial incentive to the insurance network and physicians in the healthcare practice. Also for example, as in Claims 37 and 46, the solution can be applicable to and implemented by a computer system.

5e3. Snail discloses that statistical profiles can be used to gather data and compare individual physicians to other peer physicians. Snail, however, does not disclose or teach that "incentive payments are...based on [ancillary medical] costs." Snail, page 161, lines 1-4, references a footnote which shows results of a physician compensation survey on physician group practices offering incentive-based payments. It appears to me that the Examiner is using such information to somehow extract a teaching of controlling physician behavior through use of ancillary medical costs. The data provided, however, indicates that group practice incentive payments averaged 10% of total compensation. Of this, only 10% of the 10% was based on "service and overhead costs." In other words, there was only a maximum of a 1% total impact. Further, the data provided that just over half of the Hospitals have incentive payments, which average 15% of total compensation, but there is no mention of "service and overhead costs" impact. Finally, Integrated Delivery Systems incentive payments average 5% of total compensation, and again, there is no mention of "service and overhead costs" impact. It is clearly indicated that there is only a miniscule impact of costs on incentives. *See* Snail, page 161, lines 15-30. When such factor is so diminutive, it can be expected to have little or no effect. Thus, contrary to the teachings of the Lewis Application which requires ancillary medical/pharmacy costs to be a controlling factor, even excessively high ancillary medical or pharmacy costs combined with some other factors important to Snail, would result in a maximum or near maximum incentive payment, according to Snail. Therefore, it is my opinion that one skilled in the art could not extract from this, a teaching or suggestion of utilizing ancillary medical or pharmacy costs as a method of behavior control, much less that specifically

directed to physicians in a healthcare practice participating in an insurance network (open healthcare system).

5e4. Still further, nothing indicates to me that these "costs" referred to in Snail are anything other than "those attributed directly to a medical procedure performed by a physician," which were specifically excluded in the claims, themselves, from the Applicants definition of ancillary medical costs.

5e5. Regarding Claim 1, Snail, does not disclose or teach the step of gathering data in a computer medium on ancillary pharmacy costs for each of a plurality of physicians in a healthcare practice participating in an insurance network regarding management of ancillary pharmacy costs at least primarily in the form of pharmacy costs other than those attributed by a medical procedure performed directly by any of the plurality of physicians when the respective physician directly administers a medication to a patient. Although Snail arguably describes comparing hospital-based individual practices or collective physician practices to their peers along such dimensions as resource consumption, etc., and comparing physician profiles to either general practice guidelines or to other physician practices to evaluate performance to aid in contract negotiation ("negotiation and structuring of managed care contracts"), Snail, page 156, Snail provides no such teaching of gathering data on ancillary pharmacy costs as defined in the claim.

5e6. Snail also does not disclose or teach the step of identifying from the tangible computer medium at least one of the plurality of physicians in the healthcare practice participating in the insurance network that is at a greater risk of not receiving the predetermined reimbursement amount for the ancillary pharmacy costs from the insurance network by prescribing medications that are detrimental to receiving the predetermined reimbursement amount for the ancillary pharmacy costs. This claim step has several sub-elements each individually important. First, as indicated by the Examiner, Snail does not teach the step of identifying any data from the tangible computer medium. Second, Snail does not teach application to a physician in an open healthcare system (i.e., in a healthcare practice participating in an insurance network), but rather is only directed to hospitals or possibly other closed healthcare systems. *See* Snail, abstract.

5e7. Snail also neither teaches nor suggests "substantially reducing the risk of not receiving [a] predetermined reimbursement amount for ancillary pharmacy costs from [an]

insurance network" by modifying physician behavior detrimental to such receipt, i.e., behavior outside the desires of the insurance network. Although Snail apparently identifies, again, in a hospital or closed healthcare system setting only, that use of incentive-based payments can control physician performance, it is my concerted opinion that such teaching does not transfer to the specific elements of this claim. Particularly, it is my opinion that such teaching has nothing to do with management of physician behavior with respect to the desires of the insurance network. Notably, encouraging a physician to select the cheapest pharmaceutical or forego utilization of any pharmaceutical may, altogether, not be that which is desired by the insurance network. For example, the specific pharmaceutical may be favored even though it is not necessarily the cheapest to the patient when compared to another equally suitable pharmaceutical. Snail provides no such teaching. Again, there is a significant disparity between procedures, rules, and regulations, which govern *open* healthcare systems and *closed* healthcare systems. The teachings of one simply are not directly readily transferable to the other.

5e8. Snail not only does not disclose or teach modifying ancillary pharmacy costs management behavior of one or more physicians at a greater risk regarding the ancillary pharmacy costs, substantially reducing the risk of not receiving the predetermined reimbursement amount for the ancillary pharmacy costs from the insurance network to increase the profitability of the healthcare practice; in reading Snail, one should further conclude that Snail inherently teaches away from utilization of ancillary medical costs, including pharmacy costs, to control physician behavior. One must describe this as an inherent teaching because the author of the Snail dissertation explicitly stated that the available data provided in Appendix 2 "do[es] not permit hypothesis testing." *See* Snail, page 5, lines 1-3. Thus, Snail explicitly indicates that he did not have all the facts necessary to analyze governance mechanisms in physician practice organizations or the intention to test them, making Snail generally, and Appendix 2 specifically, in combination with the knowledge generally available to one skilled in the art at the time of the invention, a non-enabling disclosure with respect to this element even if this claim was directed to a closed healthcare system.

5e9. It is my understanding that the Examiner cites Snail, pages 162-163, as indicating that, with respect to general utilization management, education is a disclosed method of modification of physician behavior. "Education," however, is only mentioned once in the context of stating that "utilization management incentives can be instilled by...the structure of

physician group practices, which encourages ongoing peer review, education, and innovation through a nonadversarial relationship." Thus, the term "education" would be interpreted by one skilled in the art to be a characteristic of the structure of physician group practices and not a utilization management mechanism. *See* also page 163, Table A2.3 (listing utilization management mechanisms but not including education as a utilization management mechanism). Further, Snail does not disclose or teach applying such education to ancillary medical or pharmacy costs to modify physician behavior with respect to such costs, or in doing so, substantially reducing the risk of not receiving the predetermined reimbursement amount for the ancillary pharmacy costs from the insurance network to increase the profitability of the healthcare practice. I have been unable to identify any passage indicating such teaching or suggestion either within or outside the pages cited by the Examiner. In my opinion, modifying physician behavior with respect to ancillary medical or pharmacy costs and substantially reducing non-reimbursement risk leading to enhanced profitability of the healthcare practice are important features correspondingly not taught by either Snail or Leet, alone, or in combination. Both features are important sub-elements; the "reducing non-reimbursement risk" feature being that which the behavior modification is directed to achieve.

5e10. The Examiner apparently introduced Leet solely to support an alleged disclosure of a tangible computer medium for gathering data regarding *physicians*. Nevertheless, as noted previously, even if there was motivation to combine Snail and Leet (which Applicants contend there is not), Leet does not "fill in the blanks" with respect to this feature or the missing features, identified above. Leet, for example, does not disclose or teach the gathering data regarding *physicians* in a healthcare group in a tangible computer medium step, or the identifying, modifying or reducing steps, even when combined with Snail. Rather, Leet teaches gathering data regarding specific diseases and treatments in order to form an intelligent diagnostic tool, which can provide "to" a physician a recommended treatment including comparative drug costs, a predicted total number of unit doses, and projected total cost of administering each recommended treatment, etc. *See* Leet, col. 3, line 41 to col 4, line 41. The Leet system can also predict an estimated cost of treating a patient with a given drug or drug combination. *See* Leet, col. 15, lines 11-28. Notably, such information can be provided "to" a *physician*, but it is <u>not</u> data regarding ancillary pharmacy/medical costs management for physicians in a healthcare group participating in an insurance network, or a teaching or

suggestion, thereof. As Leet does not disclose or teach even the element to which it was introduced by the Examiner as teaching, identified by the Examiner as missing from Snail, it is my opinion that neither Snail nor Leet, alone or in combination, provide each and every element of the independent Claims 1, 13, or 25. It is also my opinion that there is no teaching or suggestion that their combination would somehow produce the other missing elements, missing from both Snail and Leet, for the reasons provided above.

5e11. Accordingly, in view of the apparent lack of motivation to combine the teachings of Snail with that of Leet due to their noted disparities, overall failure to recognize the source of the problem as recognized by Applicants, lack of a reasonable expectation of success in developing claimed embodiments of the Lewis et al. invention even using the Lewis Application specification as a blueprint or roadmap to do so, and an apparent lack of a disclosure or teaching of each and every element of each independent claim, it is my opinion that Claims 1, 13, and 25 are novel, nonobvious and patentable over Snail in view of Leet. For similar reasons, it is also my opinion that independent system Claims 37 and 46 are novel, nonobvious, and patentable over Snail in view of Leet. It is further my opinion that the dependent claims, Claims 2-12, 14-24, and 26-36 (and Claims 39-45, and 51-56), are novel and nonobvious.

5e12. It is my opinion that neither Snail nor Leet, alone or in combination, disclose or teach gathering information regarding the ancillary pharmacy (or medical) costs of each of the plurality of physicians in the healthcare practice participating in an insurance (or medical) network, as featured, at least in part, in Claims 2 and 14. Although Leet teaches gathering drug cost data from a drug inventory and cost database (28c), the data is not aggregated pharmacy or medical costs of a *physician* or a plurality of *physicians* of a practice, as featured in the claims, but rather an estimated cost of treating a specific patient with a specific drug or drug combination. *See* Leet, col. 15, lines 11-28. Further, the Leet cost data is presented as a unique formula to rank drugs to treat a given condition (see col. 23, lines 7-8), which does not have a resulting unit of measure, because it adds both a time component, i.e., "average times drug administered per day" and cost components (see col. 23, line 19). Thus, it does not appear to even teach providing an estimated actual dollar cost of patient treatment. Correspondingly, it cannot be an aggregate pharmacy or medical cost, much less that of a plurality of *physicians* in a healthcare practice.

5e13. It is my opinion that neither Snail nor Leet, alone or in combination, nor the Examiner's official notice disclose or teach analyzing the ancillary pharmacy (or medical) costs of each of a plurality of physicians in a healthcare practice, calculating an average ancillary pharmacy (or medical) costs per physician for the healthcare practice, or identifying the physicians that have ancillary pharmacy (or medical) costs that are a predetermined percentage greater than the average ancillary pharmacy (or medical) costs per physician for the healthcare practice, as featured, at least in part, in Claims 3 and 15. The Examiner states that Snail discloses analyzing ancillary pharmacy costs. Snail, however, instead only states that "[p]hysician profiles are compared to practice guidelines for other physician practices to evaluate performance...essential to the negotiation and structuring of managed care contracts." *See* Snail, page 156, lines 6-7. These "physician profiles" are for "Selective Contracting" (page 155 Section Title) and not profiles in the management of ancillary pharmacy (or medical) costs, as featured in the claims. Snail defines "selective contracting" as "a constrained payment system in which buyers contract with a limited number of sellers based on their qualifications and prior performance, thereby establishing a competitive bidding process" (page 155, line 2-4). Snail defines "profiles" as a selective contracting tool that "compare[s] individual or collective physician practices to their peers along such dimensions as resource consumption (e.g. ancillary procedure usage), charges, and patient volumes and outcomes; some hospitals also track malpractice claims and third-party payment denials." *See* Snail, page 156, lines 1-4. Nowhere in that definition are any costs or, specifically, ancillary medical or pharmacy costs, mentioned as a measured component for selective contracting. Therefore, it is evident that the term "profiles" is used by Snail in a manner for contract management and not in a manner for ancillary cost management nor updating physicians of changes in their individual costs relative to their peers. Further, even if generally calculating averages and identifying entities were deemed to be well-known in the art of statistical profiling, as premised by the Examiner, application to physicians in a healthcare practice participating in an insurance network, with respect to ancillary medical or pharmacy costs, is not.

5e14. It is my opinion that neither Snail nor Leet disclose or teach selecting a physician having the highest ancillary pharmacy (or medical) costs within the healthcare practice, as featured, at least in part, in Claims 4 and 16. Although the Examiner cites Snail, page 156, I was unable to find any teaching or suggestion directed to such feature(s).

5e15. It is my opinion that neither Snail nor Leet disclose or teach educating the at least one physician on the benefits of alternative ancillary medical procedures or prescription medications using research literature for comparing the alternative ancillary medical procedures or medications to the current ancillary medical procedures or the prescribed medications, respectively, and organizing continued medical education classes to educate each of the plurality of physicians in the healthcare practice on the benefits of the alternative ancillary medical procedures or prescription medications, as featured, at least in part, in Claims 5 and 17. Although the Leet algorithm apparently provides a physician a recommended drug treatment according to a ranked selection, col. 14, lines 26-30, the algorithm does not provide continued medical education classes to educate each of a plurality of physicians in a healthcare practice on the benefits of the alternative insurance-network sponsored ancillary medical procedures or prescription medications. Leet, therefore, does not disclose or teach this missing feature. As such, as a matter of logic, such missing feature could not be incorporated into Snail through combination with Leet, as premised by the Examiner, to somehow produce Lewis et al.'s claimed invention.

5e16. It is my opinion that neither Snail nor Leet, alone or in combination, disclose or teach preparing a list of ancillary medical procedures or prescription medications, that at least one physician may prescribe or engage in, that enable a physician to receive the predetermined reimbursement amount for the ancillary medical or pharmacy costs, as featured, at least in part, in Claims 6 and 18. Although the Leet algorithm apparently provides a physician a recommended drug treatment according to a ranked selection, col. 14, lines 26-30, the ranking formula does not include a "predetermined reimbursement amount for ancillary pharmacy [or medical] costs" as part of its ranking criteria. *See* Leet, col. 23, lines 7-37. Leet, therefore, does not disclose or teach this missing feature. As such, as a matter of logic, such missing feature could not be incorporated into Snail through combination with Leet, as premised by the Examiner, to somehow produce Lewis et al.'s claimed invention.

5e17. It is my opinion that neither Snail nor Leet, alone or in combination, disclose or teach providing custom prescription medication or medical procedure forms that include the list of prescription medications or ancillary medical procedures, respectively, that at least one physician may prescribe or engage in that enable the at least one physician to receive the predetermined reimbursement amount for the ancillary pharmacy or medical procedure costs,

as featured, at least in part, in Claims 7 and 19. Leet discloses database information in a *closed* system database accessible using a diagnosis code (entered into a hospital record) organized into a record shown in Table III. *See* Leet, col. 10, lines 24-28 and col. 18, lines 34-40. Even if this table were considered a custom prescription or medical procedure *form*, which I do not believe would be logical, the Table III elements do not include a predetermined reimbursement amount nor such indication of reimbursement related to some drugs but not others. Leet, therefore, does not disclose or teach this missing feature. As such, as a matter of logic, such missing feature could not be incorporated into Snail through combination with Leet, as premised by the Examiner, to somehow produce Lewis et al.'s claimed invention.

5e18. It is my opinion that neither Snail nor Leet, alone or in combination, disclose or teach preparing a list of common ancillary medical procedures or prescription medications that are approved by each of the plurality of insurance networks so as to enable at least one physician to receive the predetermined reimbursement amount for the ancillary pharmacy or medical costs, as featured, at least in part, in Claims 8, 20, and 24. That is, although Leet apparently discloses providing a list of suggested medications and associated costs, Leet (and Snail) not only say nothing of having a relationship to multiple insurance networks, neither indicates a list of prescription medications or ancillary medical procedures common to such non-disclosed plurality of insurance networks, as is featured in the claims. Leet, therefore, does not disclose or teach this missing feature. As such, as a matter of logic, such missing feature could not be incorporated into Snail, through combination with Leet, as premised by the Examiner, to somehow produce Lewis et al.'s claimed invention.

5e19. It is my opinion that neither Snail nor Leet, alone or in combination, disclose or teach identifying at least one patient whose present prescription medications (or ancillary medical procedures) put the at least one physician at risk for not receiving the predetermined reimbursements for the ancillary pharmacy (or medical) costs, amending the at least one patient's present prescription medications (or ancillary medical procedures) to decrease the at least one physician's risk of not receiving the predetermined reimbursements for the ancillary pharmacy (or medical) costs, and particularly discontinuing the at least one patient's present prescription medications (or ancillary medical procedures) that put the at least one physician at risk for not receiving the predetermined reimbursements for the ancillary pharmacy (or medical) costs, as featured, at least in part, in Claims 10 and 21. Although Leet discloses

modifying the previously described drug protocol by eliminating drugs that are poorly tolerated by the community patient population or found to have an adequate *clinical effect* (col. 19, lines 30-34), this criteria is entirely *clinical criteria* which does not include a physician's risk of not receiving a predetermined reimbursement for ancillary pharmacy (or medical) costs, as featured in the claims. Leet, therefore, does not disclose or teach this missing feature. As such, as a matter of logic, such missing feature could not be incorporated into Snail through combination with Leet, as premised by the Examiner, to somehow produce Lewis et al.'s claimed invention.

5e20. It is my opinion that neither Snail nor Leet, alone or in combination, nor the Examiner's official notice, disclose or teach a physician providing a combination of *both* a first letter informing the pharmacy (or ancillary medical facility) that the at least one patient's present prescription medication (or ancillary medical procedures) is discontinued *and* the second letter informing the at least one patient that the patient's present prescription medication (or ancillary medical procedures) is discontinued, as featured, at least in part, in Claims 11 and 22. Although apparently relatively simple to implement, such dual-letter processing can readily have the effect of enhancing communication and ensuring each affected member is on the "same sheet of music."

5e21. It is my opinion that neither Snail nor Leet, alone or in combination, disclose or teach updating each of a plurality of physicians in a healthcare practice of any changes in the management of ancillary pharmacy or medical costs from the insurance network, respectively, as featured, at least in part, in Claims 12 and 23. First, neither Snail nor Leet teach or suggest procedures involving ancillary medical or pharmacy costs from an *insurance network.* Further, nowhere in the Snail definition of "profiles" are any costs or, specifically, ancillary pharmacy or medical costs as defined in the claims, mentioned as a measured component for its "selective contracting." Therefore, it is evident that the term "profiles" is used by Snail in a manner for contract management and not in a manner for ancillary cost management or updating physicians of changes in their individual costs relative to their peers. It is therefore my opinion that such feature would not be obvious to one of ordinary skill in the art at the time of the invention.

5e22. It is my opinion that neither Snail nor Leet, alone or in combination, disclose or teach the gathering, identifying, or modifying management behavior steps, as featured in Claim 25. Further, it is also my opinion that neither Snail nor Leet, alone or in

combination, disclose or teach providing a financial incentive to both an insurance network and a plurality of physicians in the healthcare practice participating in an insurance network to modify the plurality of physicians' management behavior of ancillary medical costs that are not as profitable to the insurance network. As noted previously, neither Snail nor Leet teach behavior management through ancillary medical cost reimbursements. *See* Snail page 156 and 161. Further, neither Snail nor Leet are directed to a healthcare practice participating in an insurance network. Both are directed to implementation within a closed system, e.g., hospital environment. Therefore, it is my opinion that Claim 25 is novel and nonobvious and defines over Snail in view of Leet.

5e23. It is my opinion that neither Snail nor Leet, alone or in combination, disclose or teach at least the following: a first database comprising ancillary medical procedures that are preferred by the insurance network; a second database comprising ancillary medical costs of each of the plurality of physicians participating in the insurance network; an analyzer for analyzing the data in the first and second database and comparing the ancillary medical procedures that are preferred by the insurance network with the ancillary medical costs of the plurality of physicians participating in the insurance network to thereby identify ancillary medical costs of the physicians that are not preferred by the insurance network; and managing means responsive to the analyzer for managing the ancillary medical costs of the healthcare practice identified as not being preferred by the insurance network to thereby modify the ancillary medical costs of the physicians in the healthcare practice to be more profitable to the insurance network, as featured, at least in part in Independent System Claims 37 and 46. Particularly, I have been unable to identify any passage in either Snail or Leet indicating a teaching or suggestion with respect to providing at least the following: an analyzer to compare ancillary medical procedures preferred by an insurance network with ancillary medical costs of physicians in a healthcare practice participating in the insurance network to identify those non-preferred ancillary medical costs being incurred, or managing those ancillary medical costs identified as not being preferred by an insurance network. These are apparently very important features correspondingly not taught by either Snail or Leet, or the combination thereof. It is therefore, my opinion, that Claims 37 and 46 are novel and nonobvious and define over Snail in view of Leet.

5e24. It is also my opinion that the dependent Claims 39-45, and 51-56, are also novel and nonobvious and define over Snail in view of Leet. For example, neither Snail nor Leet, alone or in combination, disclose or teach a calculating means for calculating an average ancillary medical cost per physician for the healthcare practice, etc., as featured in Claims 39 and 51; an educator as featured in Claims 40 and 52; custom medical procedure forms including ancillary medical procedures that are preferred by the insurance network, as featured in Claims 41 and 53; patient intervening means as featured in Claims 42 and 54; generating means for generating letters to both a medical facility and a patient providing notification of a change in ancillary medical procedures, as featured in Claims 43 and 55; and an updater for updating physicians in the healthcare practice of any changes in the management of ancillary medical costs, as featured in Claim 44 and 45.

5f. Long Felt Need: As described in the background section of the Lewis Application, and as observed by me, and based on my experience, there has been a long felt need to recognize the source of the problems and for a solution to the problems identified and addressed by the inventors in the Lewis Application, especially in terms of managing and optimizing profitability of the physicians in a healthcare practice participating in an insurance network by modifying the behavior of a physician for management of ancillary medical costs. Notably, as described above, neither Snail nor Leet recognize ancillary pharmacy or medical costs as a source of their problems, and this, further confirms and indicates to me that this long felt need was not met prior to the teachings in the Lewis Application including Claims 1-37, 39-46, and 51-56.

5g. Attempts by Those Skilled in the Art to Fill the Unsatisfied Need: The Background section of the Lewis Application, pp. 1-8, objectively describes attempts by those skilled in the art to analyze the healthcare industry to attempt to satisfy the long felt need. This includes use of an office manager to organize and manage medical treatment information in a manner which is preferred by an insurance network, and includes comparing healthcare provider performance. Office managers, however, can be rather expensive and often have little understanding of the relationship between a physician practice and an insurance network. Comparing provider performance can be disingenuous where healthcare costs are dependent

upon a preferred treatment of the insurance network. Because neither Snail, a dissertation examining fundamental change in hospital contracting for physician services, nor Leet, a computer implemented method and system of providing drug treatment protocols for particular disease states, have recognized the source of the problems--ancillary pharmacy or other medical costs--they have also not provided an effective solution.

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Sec. 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the publication or any patent issued thereon.

FURTHER DECLARANT SAYETH NOT.

3/16/07
Date

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